K100931

JUN 25 2010

Special 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Esaote S.p.,A
Via Siffredi 58
16153 Genova
Italy

Contact Person: Allison Scott
317.569.9500 x106
ascott@ansongroup.com

Date: April 2, 2010

807.92(a)(2)

Trade Name: 6200 System

Common Name: Ultrasound Imaging System

Classification Name(s): Ultrasonic pulse Doppler imaging system 892.1550
Ultrasonic pulsed echo imaging system 892.1560

Classification Number: 90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

K051837, K060827, K081386	6100	Esaote, S.p.A.

807.92 (a)(4)

Device Description

The 6100 is a mainframe ultrasound system, used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). The system is equipped with a LCD Color Display, a control panel and is capable of operating Linear, Convex, and Phased array probes.

The 6100 system has been cleared by FDA via K051837, K060827 and K081386.

The modified 6100, with respect to the cleared version 6100 via K051837, K060827 and K081386, is due to the improvements of the system. These modifications, that do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

a. New keyboard (control panel), where some control keys (knobs and keys) have been replaced by a touch screen.
b. New plastic housing of the system both to include the touch screen and to give a new style
c. New keyboard group PCBs lay out to interface the touch screen and to match the new organization of the panel keys.
d. Software/Firmware modification to translate the touch screen information for the software: main software characteristics and performances have not been changed.

The 6200 is the model name of the modified 6100. The set of probes of the 6100 and the 6200 is exactly the same.

The 6200 system is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 6200 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6200 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

807.92(a)(6)

Technological Characteristics

The modifications reflected in this Special 510(k) for the 6200 are intended to improve the system's performance. The modifications have not altered the fundamental scientific technology or the intended use of the unmodified version of the 6100 cleared via K051837, K060827 and K081386.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

EASOTE, S.P.A.
% Ms. Allison Scott, RAC
Regulatory Affairs Associate
The Anson Group
11460 Meridian St., Ste 150
CARMEL IN 46032

Re: K100931
Trade/Device Name: 6200 Ultrasound Imaging System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 28, 2010
Received: June 1, 2010

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 6200 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

PA230	C5-2 R13
PA240	CA123
PA122	CA430
PA023	CA431
LA332	CA541
LA435	CA631
LA522	2CW
LA523	5CW
LA923	HF CW

EC123	IOE323
EC1123	LP323
TRT33	BC431
TEE022	BL433
TEE132	BE1123

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Robert L. Becker, Jr. (for)

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

Model 6200 (Modified 6100)

Indications for Use

Special 510(k) Number (if known):

Device Name: 6200 Ultrasound Systems

Esaote's Model 6200 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6200 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the' following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

6200 (modified 6100)

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P	P	P	P	P		P		5, 6, 7, 8, 9,
Abdominal	P	P	P	P	P	P	P		P		5, 6, 7, 8, 9, 12, 13, 15
Intraoperative (Abdominal)	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 13
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P		5, 6, 7, 8, 9, 12, 13
Small Organ [1]	P	P	P	P	P	P	P		P		5, 6, 7, 8, 9, 12, 14
Neonatal Cephalic	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Adult Cephalic	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Adult Cardiac	P	P	P	P	P	P	P	P	P	P	5, 6, 7, 8, 9, 10, 11, 12
Pediatric Cardiac	P	P	P	P	P	P	P	P	P		5, 6, 7, 8, 9, 10, 11, 12
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Non Cardiac)											
Transrectal	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 13, 14
Transvaginal	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 13, 15
Laparoscopic	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 13
Musculo-skeletal Conventional [3]	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 13, 14, 15
Musculo-skeletal Superficial [3]	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 13, 14,
Other (Urological)	P	P	P	P	P	P	P		P		5, 6, 8, 12, 13, 15

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block-

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] CMM
[6] 3D
[7] 4D
[8] VPan
[9] XView
[10] Stress
[11] Xstrain
[12] Compound Imaging (Mview)
[13] TP-View
[14] Elastography
[15] Virtual Navigator

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

6100 Previously cleared via k051837, K060827 and k081386

Prescription Use Only Per 21 CFR 801 Part D
Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - PA230

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Abdominal	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 15
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Adult Cardiac	P	P	P	P	P	P	P	P	P	P	6, 8, 9, 10, 11, 12
Pediatric Cardiac	P	P	P	P	P	P	P	P	P		6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging (Mview)

[15] Virtual Navigator

Previously cleared via k091009

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - PA240

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P	P	P	P	P		P		5, 6, 8, 9
Abdominal	P	P	P	P	P	P	P		P		5, 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P		5, 6, 8, 9
Small Organ [1]	P	P	P	P	P	P	P		P		5, 6, 8, 9
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P		P		5, 6, 8, 9
Adult Cardiac	P	P	P	P	P	P	P	P	P	P	5, 6, 8, 9,
Pediatric Cardiac	P	P	P	P	P	P	P	P	P		5, 6, 8, 9,
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P		5, 6, 8, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are: B+M+PW+CW+CFM+PD

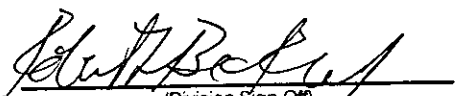
[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain



(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 15100931

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - PA122

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]											
Neonatal Cephalic	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Adult Cephalic											
Cardiac [2]	P	P	P	P	P	P	P	P	P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain

[15] Virtual Navigator

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - PA023

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]											
Neonatal Cephalic	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Adult Cephalic											
Cardiac [2]	P	P	P	P	P	P	P	P	P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

[9] XView

[10] Stress

[11] Xstrain

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - LA332

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12,
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12,
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]	E	E	E		E	E	E		E		6, 8, 9, 10, 11, 12, 13
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12,
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

[13] TP-View

[14] Elastography

Previously cleared via k091009

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - LA435

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12,
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12,
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12, 14, 13
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14, 15
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14, 15
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging

[13] TP-View

[14] Elastography

[15] Virtual Navigator

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K k100931

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - LA522

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12,
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14, 15
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14, 15
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging

[13] TP-View

[15] Virtual Navigator

[14] Elastography

[15] Virtual Navigator

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K 15100931

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - LA523

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12,
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12,
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]	E	E	E		E	E	E		E		6, 8, 9, 10, 11, 12, 13
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14, 15
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14, 15
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

[13] TP-View

[14] Elastography

[15] Virtual Navigator

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - LA923

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12,
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12,
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12,
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12,
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging

[13] TP-View

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

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Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - C5-2 R13

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Other (Urological)	P	P	P		P	P	P		P		5, 6, 8, 9, 12

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - CA123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Neonatal Cephalic	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 8, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block-

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

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Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100931

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Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - CA430

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12, 15
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Other (Urological)	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

[15] Virtual Navigator

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Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - CA431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Other (Urological)	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

[15] Virtual Navigator

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Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - CA541

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	N	N	N		N	N	N		N		5, 6, 8, 9, 12
Abdominal	N	N	N		N	N	N		N		5, 6, 8, 9, 12, 15
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	N	N	N		N	N	N		N		5, 6, 8, 9, 12
Small Organ [1]	N	N	N		N	N	N		N		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	N	N	N		N	N	N		N		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	N	N	N		N	N	N		N		5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	N	N	N		N	N	N		N		5, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	N	N	N		N	N	N		N		5, 6, 8, 9, 12, 15
Other (Urological)	N	N	N		N	N	N		N		5, 6, 8, 9, 12, 15

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

[15] Virtual Navigator

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Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - CA631

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Abdominal	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Small Organ [1]	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Neoriatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15
Other (Urological)	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 15

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

[15] Virtual Navigator

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Office of In Vitro Diagnostic Device Evaluation and Safety

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Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - 2CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]				P							
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular				P							
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: CW

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Previously cleared via k091009

Prescription Use Only Per 21 CFR 801 Part D Concurrence
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6200 (Modified 6100) - 5CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular				P							
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

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510K k100931

[4] Combined modes are: CW

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6200 (Modified 6100) - HF CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular				N							
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are: CW

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510K K100931

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

6200 (Modified 6100) - EC123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P		P		6, 8, 9, 12
Transvaginal	P	P	P		P	P	P		P		6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P	P	P	P	P		P		6, 8, 9, 12, 15

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are:
B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging

[15] Virtual Navigator

Previously cleared via k091009

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Prescription Use Only Per 21 CFR 801 Part D Concurrence
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6200 (Modified 6100) - EC1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P		P		5, 6, 8, 9, 12, 14
Transvaginal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P	P	P	P	P		P		5, 6, 8, 9, 12

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are:
B+M+PW+CFM+PD

[5] CMM

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging

[14] Elastography

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6200 (Modified 6100) - TRT33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	E	E	E		E	E	E		E		6, 8, 9, 12,
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Transvaginal	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are:B+M+PW+CFM+PD
[5] CMM
[6] 3D
[8] VPan
[9] XView
[12] Compound Imaging
[13] TP-View
[14] Elastography

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6200 (Modified 6100) - TEE022

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P		5, 6, 9, 10,
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are:
B+M+PW+CW+CFM+PD
[5] CMM
[6] 3D
[9] XView
[10] Stress
[11] Xstrain

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6200 (Modified 6100) - TEE132

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)	P	P	P	P	P	P	P	P	P		5, 6, 9, 10,
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are:
B+M+PW+CW+CFM+PD
[5] CMM
[6] 3D
[9] XView
[10] Stress
[11] Xstrain

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6200 (Modified 6100) - IOE323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 8, 9, 12,
Abdominal	P	P	P		P	P	P		P		6, 8, 9, 12,
Intraoperative (Abdominal)	P	P	P		P	P	P		P		6, 8, 9, 12,
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 8, 9, 12,
Small Organ [1]	P	P	P		P	P	P		P		6, 8, 9, 12, 13, 14
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12,
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging

[13] TP-View

[14] Elastography

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6200 (Modified 6100) - LP323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 8, 12,
Abdominal	P	P	P		P	P	P		P		5, 6, 8, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 8, 12,
Small Organ [1]	P	P	P		P	P	P		P		5, 6, 8, 12,
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 12,
Laparoscopic	P	P	P		P	P	P		P		5, 6, 8, 12,
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are: B+M+PW+CW+CFM+PD

[6] 3D

[8] VPan

[9] XView

[12] Compound Imaging

[13] TP-View

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6200 (Modified 6100) - BC431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhancement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 12
Abdominal	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 12
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 12
Small Organ [1]	E	E	E		E	E	E		E		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	P	P	P		P	P	P		P		5, 6, 7, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		5, 6, 8, 9,12
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		5, 6, 8, 9,12
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		5, 6, 8, 9,12
Other (Urological)	P	P	P		P	P	P		P		6, 6, 8, 9, 12

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[7] 4D

[9] XView

[10] Stress

[11] Xstrain

[12] Compound Imaging

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6200 (Modified 6100) - BL433

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		6, 7, 8, 9, 12, 13
Abdominal	P	P	P		P	P	P		P		6, 7, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	P	P		P	P	P		P		6, 7, 8, 9, 12, 13
Small Organ [1]	P	P	P		P	P	P		P		6, 7, 8, 9, 12, 13
Neonatal Cephalic	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Laparoscopic											
Musculo-skeletal Conventional [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	P	P	P		P	P	P		P		6, 8, 9, 12, 13
Other (Urological)	P	P	P		P	P	P		P		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[7] 4D

[9] XView

[12] Compound Imaging

[13] TP-View

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6200 (Modified 6100) - BE1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

	Mode of Operations										
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	P	P	P		P	P	P		P		5, 6, 7, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Transvaginal	P	P	P		P	P	P		P		5, 6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	P	P	P		P	P	P		P		5, 6, 9, 12

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are:
B+M+PW+CFM+PD

[5] CMM

[6] 3D

[9] XView

[12] Compound Imaging

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